

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF NEW YORK

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WELCH ALLYN, INC.,

Plaintiff,

Civil Action No.  
5:14-CV-1122 (TJM/DEP)

v.

OBP CORPORATION and OBP  
MEDICAL INC.,

Defendants.

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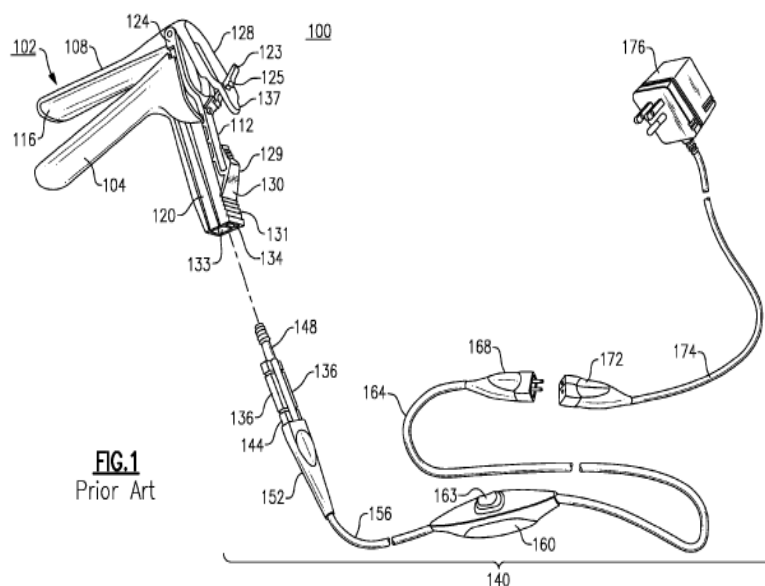
## AMENDED REPORT AND RECOMMENDATION

This is an action involving competitors engaged in the manufacture and marketing of medical products. A significant portion of the instant controversy surrounds a patent issued to several inventors and assigned to plaintiff Welch Allyn, Inc. ("Welch Allyn"), disclosing an innovative vaginal speculum apparatus. Welch Allyn, a business headquartered in Upstate New York, contends that vaginal specula sold by defendants OBP Corporation and OBP Medical Inc. (collectively "OBP"), two Massachusetts-based medical products companies, infringe the claims of the patent in suit. Welch Allyn also asserts claims of trade dress infringement, unfair competition, and deceptive business practices under federal and state law arising out of OBP's sale of the accused products.

Despite their best efforts, the parties have been unable to agree on the proper construction of several terms included within the patent claims asserted by Welch Allyn in the action. The issue of claim construction has been referred to me for the issuance of a report and recommendation. Based on the parties' written submissions and an in-person claim construction hearing, the following sets forth my recommendations concerning those contested claims.

## I. BACKGROUND

The patent infringement claims asserted in this action concern United States Patent No. 8,435,175 ("175 Patent"), entitled "Vaginal Speculum Apparatus" and issued on May 7, 2013 to nine inventors, who in turn have assigned the patent to Welch Allyn. Dkt. No. 1 at 1, 3. The patent discloses advancements in the design of a vaginal speculum, a device commonly known and used "in the field of diagnostic medicine for purposes of examining the cervix of a female patient." '175 Patent, 1:28-30. A vaginal speculum is typically comprised of an upper blade member and a lower blade member, oriented to open and close by means of an articulation mechanism in order to dilate the vaginal cavity of a patient. *Id.* at 1:30-34. To enhance the effectiveness of a vaginal speculum, a light source is often utilized in conjunction with the device to illuminate the area being examined. *Id.* at 1:35-52. Historically, that illumination was provided by means of a small light source such as a halogen or other miniature incandescent lamp. *Id.* at 1:38-43. A representative speculum designed in accordance with the prior art is depicted in Figure 1, set forth below:



**FIG. 1**  
Prior Art

'175 Patent Fig. 1. Figure 1 reflects a disposable speculum **102** and reusable light assembly **140**. '175 Patent, 6:60-62. The speculum **102** is comprised of three interconnected components, including a lower blade member **104**, an upper blade member **108**, and a slide member **112**. *Id.* at 6:62-65. A handle portion **120** extends vertically downward from the proximal, or rear, end of the lower blade member **104**, and is integrally molded to the lower blade member. *Id.* at 7:3-6. An intermediate portion of the slide member **112** is fitted within a guide slot provided on a rearward facing side of the handle portion **120**, with the slide member further having a forked upper end or yoke **124** that receives the upper blade member **108** and is pivotally attached thereto, including a downwardly extending lever

portion **128** extending from the proximal end of blade member.<sup>1</sup> '175

Patent, 7:7-13. The handle portion of **120** of the disposable speculum **100** includes a receiving cavity **133** that is sized for receiving a housing **144** of a reusable illumination assembly **140**. *Id.* at 7:40-43. The housing **144** retains a miniature incandescent lamp, such as a halogen bulb, which is sealingly retained within a distal portion **148** thereof. *Id.* at 7:43-45.

The invention disclosed in the '175 Patent is intended to overcome several deficiencies associated with the prior art. Some earlier specula, for example, made use of a corded assembly, thereby eliminating or reducing the portability of the device and making it more difficult to examine patients, particularly bed-ridden patients in remote locations. '175 Patent 2:17-29. In addition, the light sources typically found in earlier specula created "hot spots" and produced a reflection of light back into the eye of the user, causing a glare and impairing the effectiveness of the examination. *Id.* at 1:53-59. Light sources in certain earlier specula also were situated in such a way as to obstruct the view of the user. *Id.* at 1:64-66. Moreover, bodily fluids expelled during the examination were often trapped by the light source, causing contamination and buildup against the

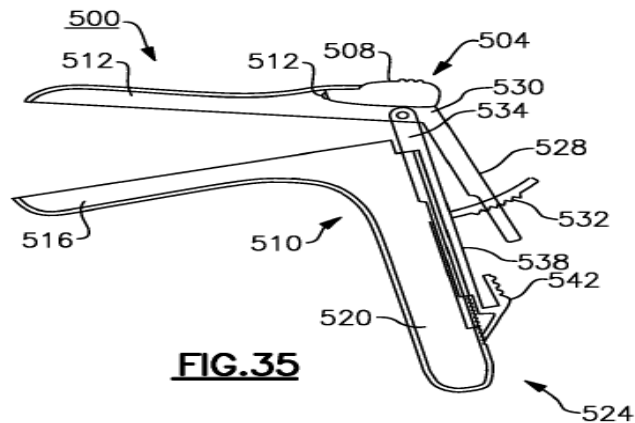
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<sup>1</sup> The lever portion **128** includes an opening **135**, which is not shown in Figure 1, defining a user aperture for use by the examiner between the yoke **124** and the lower and upper blade members **104**, **108**. '175 Patent, 7:14-16.

light-emitting surface of the light pipe and reducing the effectiveness of the examination. *Id.* at 2:11-16.

The shortcomings associated with prior art specula were addressed by the '175 Patent inventors, who devised a fully disposable instrument that utilizes a portable cartridge, including an LED light source and batteries, than can be releasably attached to the speculum and can be located in either the upper or lower blade. Dkt. No. 39-2 at 4-5; *see also* '175 Patent, 2:42-50. The illumination cartridge can be removable and can either be turned on automatically when inserted into one of the speculum blades, or instead activated through use of a switch or other similar mechanism. Dkt. No. 39-2 at 4; '175 Patent, 3:65 – 4:5, 4:61-64. In addition, the inventors conceived of including a removable light pipe or prism for use in transmitting light from the LED source to the examination area. Dkt. No. 39-2 at 4; '175 Patent, 3:31-32, 5:3-4

A representative embodiment of the invention disclosed in the '175 Patent is depicted in Figure 35, set forth below.



'175 Patent Fig. 35. In this embodiment, an illumination assembly **504** comprising a compact housing **508** is disposed within the top blade **512** of the speculum in a manner such that the light source, LED or otherwise, is aligned along the longitudinal axis of the top blade **512**. '175 Patent, 22:60-66. The speculum includes an upper blade **512** and a lower blade **516**, the latter of which includes a downwardly depending handle portion **520**. *Id.* at 22:66 – 23:2. An articulation mechanism **524** is included, consisting of a lever portion **528** extending from a proximal end **530** of the top blade **512** and is engageable with teeth provided on a flexible projection **532** extending outwardly from the lower portion of a yoke **534** of a slide member **538**. *Id.* at 23:2-7. A patient is dilated for purposes of this embodiment by use of a lower tongue **542** that enables adjustable movement of the slide member **538** along the exterior of the handle portion **520**, in turn permitting relative movement between the blades **512**,

**516.** *Id.* at 23:7-10. In this embodiment, the housing **508** can be reusable or expendable, and contains at least one battery and necessary circuitry for powering the LED. *Id.* at 23:10-13. While the housing **508** is releasably attached to the top blade **512** in this embodiment, it can alternatively be positioned relative to either the top blade **512** or the lower blade **516** of this speculum **510**. *Id.* at 12-16.

Although not specifically explained in the '175 Patent's specification, the parties agree that the end where the upper and lower blades open is referred to as the distal end and the opposite end of the speculum – that which is closest to the user of the speculum – is known as the proximal end. Dkt. No. 54 at 117, 120; see *also* '175 Patent, 7:3-6 (explaining that the handle extends downward "from the proximal or rear end of the lower blade member").

## II. PROCEDURAL HISTORY

Plaintiff commenced this action on September 12, 2014. Dkt. No. 1. In its complaint, Welch Allyn alleges that OBP makes, uses, sells, offers to sell, and/or imports vaginal specula and kits that include such specula, which practice the '175 Patent. *Id.* at 3. In addition, Welch Allyn contends that by replicating its color coded system intended to identify and distinguish the various sizes of specula available, OBP has engaged in



trade dress infringement, unfair competition, and deceptive business practices in violation of 15 U.S.C. § 1125(a), N.Y. Business Law § 349, and New York State common law. *Id.* at 4-11. OBP has since answered, denying plaintiff's allegations, asserting various affirmative defenses including, *inter alia*, patent invalidity, inequitable conduct, and estoppel, and counterclaiming seeking declarations of unenforceability and invalidity. Dkt. No. 17.

In accordance with the court's local patent rules, the parties have conferred and submitted a joint claim construction statement revealing their disagreement concerning several claim terms contained within the '175 Patent. Dkt. No. 36. The issue of claim construction has been referred to me for the issuance of a report and recommendation pursuant to 28 U.S.C. § 636(b)(1)(B). Dkt. No. 41. In accordance with that referral, a claim construction hearing was conducted on August 19, 2015. Text Minute Entry Dated Aug. 19, 2015. At the conclusion of that hearing, I reserved decision and indicated that I would provide a written report and recommendation to Senior District Judge Thomas J. McAvoy concerning the issue of claim construction. *Id.*

### III. DISCUSSION

#### A. Claim Construction: The Legal Framework

Patent claim construction presents an issue of law, to be decided by the court. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1329 (Fed. Cir. 2012); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*); see also *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1366 (Fed. Cir. 2004) ("The meaning and scope of patent claim terms, as determined by a district court's claim construction rulings, are legal issues central to most patent cases."). "Claim construction is a legal statement of the scope of the patent right; it does not turn on witness credibility, but on the content of the patent documents." *Lighting Ballast Control, LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1284 (Fed. Cir. 2014) (*en banc*).

As a general rule, a court tasked with construing a patent must assign claim terms their ordinary and customary meanings, as understood by a person of ordinary skill in the art when read in the context of the patent specification and prosecution history.<sup>2</sup> *Butamax(TM) Advanced*

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<sup>2</sup> In his declaration, Welch Allyn employee Scott G. Spanfelner has offered the following observation with regard to a person of ordinary skill in the art:

The art involved in the '175 Patent is the design, manufacture or utilization of vaginal specula, which involve

*Biofuels LLC v. Gevo, Inc.*, 746 F.3d 1302, 1308-09 (Fed. Cir. 2014); *Thorner v. SONY Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313; *accord*, *Thorner*, 669 F.3d 1365; *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("Generally speaking, we indulge a

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mechanical, electrical and optical elements. Given the different technical disciplines involved, the design of vaginal specula is an interdisciplinary and collaborative effort. The scope of knowledge and skills available to persons of ordinary skill working in this art at the time of the invention at issue in this case would have included, in addition to their own educational background and training, working knowledge about the types of uses made of vaginal specula by physicians, obstetricians, gynecologists, and other medical practitioners. Thus, persons having ordinary skill in the art at the time of the invention would have included engineers working collaboratively and having among them at least a bachelor's degree in biomedical, technical, mechanical, optical and/or electrical engineering, several years of experience in designing, testing or manufacturing diagnostic medical devices, and several years of experience working in the healthcare industry.

Dkt. No. 39-2 at 2. OBP's expert, Carl Leinsing, has countered by opining that, "[i]n [his] opinion one of ordinary skill in the art in 2005 would be an individual with a Bachelor's Degree in mechanical engineering or equivalent technical degree and at least 5 years of experience in the medical device field." Dkt. No. 38 at 17.

'heavy presumption' that a claim term carries its ordinary and customary meaning.").

There are two exceptions to this general rule. The first involves a circumstance in which a patentee has acted as its own lexicographer, setting out a definition of a term that differs from its ordinary and customary meaning. *Butamax(TM)*, 746 F.3d at 1309; *Thorner*, 669 F.3d at 1365. "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Thorner*, 669 F.3d at 1365 (quoting *CCS Fitness, Inc.*, 288 F.3d at 1366); accord, *Aventis Pharma S.A.*, 675 F.3d at 1330. Under the second exception, a claim term may also properly be given a meaning that differs from its customary meaning "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Butamax(TM)*, 746 F.3d at 1309 (quoting *Thorner*, 669 F.3d at 1366); accord, *Aventis Pharma S.A.*, 675 F.3d at 1330. These two exceptions to the rule that patent terms should be given their ordinary meaning are both narrow and exacting. *Thorner*, 669 F.3d at 1366-67.

While the words of a patent claim will generally control, they should not be interpreted in isolation; "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular

claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. A patent's specification often constitutes the "single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582. In this respect, a patent specification, which some liken to an internal dictionary, must be carefully reviewed to determine whether, for example, the inventor has used a particular term in a manner inconsistent with its ordinary meaning. *Id.* When resorting to a patent's specification for guidance with respect to disputed claim terms, a court must consider it as a whole, and where possible, all portions should be read in a manner that renders the patent internally consistent. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379-80 (Fed. Cir. 2001).

Although the language of a patent specification can provide important clues regarding the proper construction to be accorded to a claim term, there are limitations upon its usefulness. "[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988) (emphasis in original). "Nor should particular embodiments in the specification be read into the claims; the general rule

is that the claims of a patent are not limited to the preferred embodiment." *Cornell Univ. v. Hewlett-Packard Co.*, 313 F. Supp. 2d 114, 126 (N.D.N.Y. 2004) (Mordue, J.) (citing, *inter alia*, *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204 (Fed. Cir. 2002)).

In addition to the ordinary meaning of a claim term itself and the patent's specification, the prosecution history related to the patent in issue can help inform the determination of a proper claim term construction. *Phillips*, 415 F.3d at 1314. That history is generally comprised of "the complete record of proceedings before the Patent and Trademark Office [("PTO")], including any express representations made by the applicant regarding the intended scope of the claims," and an examination of any relevant prior art. *Vitronics*, 90 F.3d at 1582-83. Such evidence, which typically chronicles the dialogue between the inventor and the PTO leading up to the issuance of a patent, and thus can act as a reliable indicator of any limitations or concessions on the part of the applicant, oftentimes proves highly instructive on the issue of claim construction. See *Phillips*, 415 F.3d at 1317 ("[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in

the course of prosecution, making the claim scope narrower than it would otherwise be.").

As is discussed above, the focus of the claim construction exercise is upon the understanding of a person of ordinary skill in the art at the time of the invention as to the ordinary and customary meaning of the claim terms, considered in the context of the patent specification and prosecution history. *Butamax(TM) Advanced Biofuels LLC v. Gevo, Inc.*, 746 F.3d 1302, 1308-09 (Fed. Cir. 2014). Such extrinsic evidence as expert declarations, particularly in the wake of *Phillips*, has been relegated to the role of a secondary sources in the claim construction hierarchy. As explained by the Federal Circuit in *Phillips*,

[E]xtrinsic evidence in the form of expert testimony can be useful to a court for, *inter alia*, 'establish[ing] that a particular term in the patent or the prior art has a particular meaning in the pertinent field. However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.'

*Phillips*, 415 F.3d at 1318 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard, Co.*, 182 F.3d 1298, 1308-09 (Fed. Cir. 1999)); *see also Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1361 (Fed. Cir. 2013).

B. Parties' Objections to Declarations Submitted to the Court

Both parties have submitted extrinsic evidence in connection with the claim construction undertaking. With its opening claim construction brief, Welch Allyn submitted the declarations of Tracy L. Bennett, the company's Manager of Women's Health, and Scott G. Spanfelner, the Director of Enterprise Program Management at Welch Allyn.<sup>3</sup> Dkt. Nos. 39-1, 39-2. Later, in response to OBP's opening claim construction submission, Welch Allyn submitted a supplemental declaration from Spanfelner. Dkt. No. 47-1. OBP objects to the submission of those declarations and has moved to strike them, arguing that Welch Allyn failed to comply with the requirements of the court's local patent rules. Dkt. No. 44 at 9.

For its part, OBP submitted both an opening and a supplemental expert declaration of Karl R. Leinsing, a retained engineering and design expert. Dkt. Nos. 38, 45. While Welch Allyn has not formally moved to strike Leinsing's declarations, it argues that they should be given no weight because they represent a proxy for oral argument concerning claim construction, transparently disguised as an expert declaration purporting

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<sup>3</sup> Spanfelner is one of the named inventors of the '175 Patent.



to inform the court how a person of ordinary skill in the art would construe certain terms. Dkt. No. 47 at 7-8.

While expert testimony may be accepted by a court for the purpose of claim construction, the expert opinions must satisfy the requirements of Rule 702 of the Federal Rules of Evidence, as well as governing standards under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993), and its progeny.<sup>4</sup> See, e.g., *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1356 (Fed. Cir. 2001) (finding no error in the district court's reliance on an expert in rendering a claim construction decision where the expert's testimony comported with Rule 702 and *Daubert*).

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<sup>4</sup> Rule 702 provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In addition to meeting the requirements of Rule 702 and *Daubert*, expert testimony submitted in connection with the claim construction must conform to the court's local patent rules and satisfy the general relevance standard of Rule 401 of the Federal Rules of Evidence. Rules 4.3 and 4.4 of the court's local patent rules govern, *inter alia*, the exchange of information regarding claim construction in anticipation of a *Markman* hearing. In particular, Rule 4.3 provides, in relevant part, as follows:

(b) At the same time the parties exchange their respective Preliminary Claim Constructions, each party shall also identify all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including expert witnesses. Extrinsic evidence shall be identified by production number or by producing a copy if not previously produced. With respect to all witnesses including experts, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction.

N.D.N.Y. L.P.R. 4.3(b). Similarly, Rule 4.4, which governs the preparation of the filing of a joint claim construction and prehearing statement, provides as follows:

(a) Not later than twenty-one (21) days after the exchange of Preliminary Claim Constructions under Local Patent Rule 4.3(a), the parties shall complete

and file a Joint Claim Construction and Prehearing Statement, which shall contain the following information: . . .

- (2) Each party's proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that construction, and an identification of any extrinsic evidence known to the party upon which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including experts[.]

N.D.N.Y. L.P.R. 4.4(a)(2). As can be seen, these rules require advance disclosure of witness testimony to be offered in connection with claim construction.

The opening Bennett and Spanfelner declarations, as Welch Allyn argues, appear to relate to the state of the art and vaginal specula generally, and provide only background information concerning those subjects and the '175 Patent. More troublesome is the supplemental Spanfelner rebuttal affidavit, which appears to be offered to support Welch Allyn's proposed claim term constructions. Since Spanfelner was not disclosed as a witness, expert or otherwise, who would be offered to support Welch Allyn's claim constructions, the submission of his

declaration could be viewed as a technical violation of Rules 4.3 and 4.4 of the court's local patent rules, described above.<sup>5</sup>

Before striking the supplemental Spanfelner affidavit on this ground, the court must determine whether such drastic relief is warranted.

Generally, an expert report that does not meet procedural requirements should be excluded. See, e.g., Fed. R. Civ. P. 37(c)(1); see also *Advanced Fiber Techs. Trust v. J & L Fiber Servs., Inc.*, No. 07-CV-1191, 2010 WL 1930569, at \*2 (N.D.N.Y. May 11, 2010) (Kahn, J.). While, by its literal terms, Rule 37(c)(1) appears to be rather stringent in its exclusionary requirements, the Second Circuit has nonetheless moderated its impact by outlining certain relevant factors to be considered when determining whether to preclude expert testimony, including (1) the explanation given for failing to comply with the operative discovery order; (2) the importance of the testimony at issue; (3) whether prejudice would be suffered by the opposing party in having to respond to the new testimony; and (4) the possibility of a continuance. *Softel, Inc. v. Dragon Med. & Sci. Commc'ns*,

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<sup>5</sup> To the extent that the local rules may be ambiguous with respect to this issue, I conclude that, where indefiniteness is raised in the context of claim construction, the patentee need not produce expert disclosure in connection with its claim construction submissions mandated under Rule 4.3.

*Inc.*, 118 F.3d 955, 961 (2d Cir. 1997) (citing *Outley v. City of N.Y.*, 837 F.2d 587, 590-91 (2d Cir. 1988)).

In this instance, consideration of these factors weighs in favor of permitting the Spanfelner declaration to stand. The declaration was submitted in response to OBP's argument that certain claims of the '175 Patent are invalid. Invalidity is affirmative defense, upon which OBP bears the burden of proof. *Spotless Enter., Inc. v. A & E Prods. Grp. L.P.*, 294 F. Supp. 2d 322, 344 n.19 (E.D.N.Y. 2003) (citing *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377 (Fed. Cir. 2002)). Because the issue was first interjected by OBP in its opening claim construction brief, and Welch Allyn arguably could not have anticipated the invalidity argument being made in connection with claim construction, fairness dictates that it be given the opportunity to respond to the allegations of invalidity. With respect to the importance of the Spanfelner testimony, while it is somewhat enlightening on the issues, the '175 Patent specification, to which he refers, is far more persuasive than his conclusions. In any event, the court is unable to discern any prejudice that would be suffered by OBP if the Spanfelner declarations are permitted to stand. Despite being aware of his existence and the fact that he was providing declarations with respect to claim construction, OBP chose not to take his deposition prior to the *Markman*

hearing. While the court has considered the possibility of a continuance and concludes that it is not a suitable alternative, I also find it unnecessary to ameliorate any potential prejudice. Based upon the foregoing, I am not inclined to strike any of the three declarations at issue, and instead recommend that the court afford them the weight that, in its discretion, it finds they deserve.<sup>6</sup>

Turning to the Leinsing declarations offered by OPB, as Welch Allyn argues, those declarations, particularly the principal declaration, contain argument as to how certain of the claim terms in dispute should be construed and assert that a person of ordinary skill in the art would understand the construction proposed by OBP to be proper in light of the '175 Patent specification. Such argument, stated as it is in wholly conclusory fashion, without more, is unhelpful to the court. See *Phillips*, 415 F.3d at 1318 ("[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court."); accord, *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1361 (Fed.

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<sup>6</sup> Speaking to the issue of relevance, I recommend the court consider all three of the declarations at issue insofar as they relate to claim construction, as opposed to background information that does not influence the construction process to the extent permitted under *Phillips*. While OBP argues that the declarations contain improper expert opinions, it does not explain why those declarations fail to satisfy the requirements of Rule 702 and *Daubert*. Spanfelner is both an inventor of the '175 Patent, as well as a person of ordinary skill in the art. Spanfelner's opinions should therefore be considered, and given such weight as the court deems appropriate.

Cir. 2013). While the declaration unduly encroaches upon the court's prerogative, Welch-Allyn has not moved to strike it. Dkt. No. 54 at 3. Accordingly, I will not recommend that such relief be granted but will, however, recommend that the declaration be considered only to the extent it offers meaningful and supported opinions as to how a person of ordinary skill in the art would construe certain disputed terms.

C. Indefiniteness

Before turning to the disputed claim terms, as a threshold matter, I will first address OBP's argument that certain of them are indefinite. As is relevant here, 35 U.S.C. § 112, ¶ 2, requires that a patent's specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."<sup>7</sup> 35 U.S.C. § 112, ¶ 2; *Nautilus, Inc.*, 134 S. Ct. at 2125. "A lack of definiteness renders invalid 'the patent or any claim in suit.'" *Nautilus, Inc.*, 134 S. Ct. at 2125 (quoting 35 U.S.C. § 282, ¶ 2(3)).

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<sup>7</sup> As a result of the enactment of the Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 285 (2011), certain portions of the Patent Act, including section 112, have been restructured. Section 112, ¶ 2 was one of the sections amended, in minor respects, and is now codified at 35 U.S.C. § 112(b). The amendment to section 112, however, became effective only with regard to patent applications filed after September 16, 2012. *Nautilus, Inc.*, 134 S. Ct. at 2125, n.1. Because the application that matured into the '175 Patent was filed on April 26, 2012, I will cite to the version of section 112 effective in 2006.

It is not clear whether a court should address indefiniteness during claim construction proceedings or later, either at the summary judgment stage or during a trial. Adding to the confusion, the Federal Circuit has suggested that indefiniteness is a matter that "go[es] to claim *validity*," *Intervet Am., Inc. v. Kee-Vet Labs.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (emphasis in original), yet is also "inextricably intertwined with claim construction[.]" *Amtel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999); see also *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1367 (Fed. Cir. 2001) ("The question of whether the claims meet the statutory requirements of § 112 ¶ 2 is a matter of construction of the claims, and receives plenary review on appeal."); *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998) ("A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims."). These cases, and the absence of explicit guidance from either the Supreme Court or Federal Circuit, have engendered confusion regarding whether a district court should address indefiniteness at the time it conducts its claim construction analysis, or whether it should do so at a later procedural stage. See, e.g., *Indus. Tech. Research Inst. v. LG Elecs. Inc.*, No. 13-CV-2016, 2014 WL 6907449, at \*2 (S.D. Cal. Dec. 8, 2014)



("To begin with, the Court recognizes the uncertainty that exists as to whether indefiniteness should be addressed during claim construction proceedings or the summary judgment stage."); *ASM Am., Inc. v. Genus, Inc.*, No. 01-CV-2190, 2002 WL 1892200, at \*15-16 (N.D. Cal. Aug. 15, 2002) ("There is some ambiguity in the case law as to whether a finding of indefiniteness should occur during claim construction, or whether it should occur at a later step."). Adding to the confusion is the fact that, in two of the instances where the Federal Circuit has suggested that indefiniteness is appropriately addressed during claim construction, the court was reviewing a district court's decision on summary judgment. *Amtel Corp.*, 198 F.3d at 1375-76; *S3 Inc.*, 259 F.3d 1365. That guidance, without further explanation, seems misplaced in the context of an appeal from a district court's summary judgment decision.

In any event, without deciding which is the better course as a general principle, I recommend that the court decline to address OBP's arguments regarding indefiniteness. As will be discussed below, I find that some of the disputed terms need no further refinement, while others are amenable to construction. Although a court may be forced to engage in an indefiniteness analysis at the claim construction phase when "reasonable efforts at claim construction prove futile," *Inova Diagnostics, Inc. v. Euro-*

*Diagnostica AB*, No. 08-CV-0845, 2009 WL 2602608, at \*4 (S.D. Cal. Aug. 24, 2009) (quotation marks omitted), those circumstances are not present here.<sup>8</sup> Accordingly, I recommend that the court decline OPB's invitation in this case to determine at this juncture whether any of the disputed terms are indefinite under section 112 and leave that issue for resolution at a later stage in the proceedings.

D. Claim Construction Analysis

In their joint claim construction statement, the parties identified sixteen separately disputed claim terms. Dkt. No. 36-1. Since the filing of that document, however, they have reached agreement concerning five of those terms, as follows:

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<sup>8</sup> Of course, that a disputed term is merely amenable to construction does not necessarily render the limitations valid under section 112. See *Nautilus, Inc.*, 134 S. Ct. at 2130 ("It cannot be sufficient that a court can ascribe *some* meaning to a patent's claims.").

<u>Term/Phrase</u>	<u>Claim</u>	<u>Agreed Construction</u>
integral curved light pipe	1	a component of the portable illumination assembly that transmits light
receives	1	the handle portion itself (not some other component) holds or contains a portion of the portable illumination assembly
set of rails	6	a pair of substantially straight structures (for example, a track) on the handle portion that aligns and retains a portion of the portable illumination assembly
housing	1	an enclosure that retains the portable power supply
within a common housing	9, 18	an enclosure that retains within it the components of the portable illumination assembly

Dkt. No. 39 at 12 n.1; Dkt. No. 54 at 12-14. In light of the parties' agreement, I recommend that the court adopt the agreed-upon constructions set forth above.

Remaining before the court are the following ten claim terms requiring construction:

<u>Term/Phrase</u>	<u>Claims Implicated</u>
switch	4, 15, 19
mechanism for energizing	3, 9, 18
said speculum is disposable	7, 11
the entire apparatus is disposable	8, 12
said illumination assembly is accessed . . . through said opening	9
can be accessed . . . only through said defined opening	18
lower blade	1, 9, 18
handle portion	1, 14
releasably attached	1, 9
portable illumination assembly	1, 9, 18
proximal end (of the lower blade)	9, 18

In this action, Welch Allyn has accused OBP of infringing claims 1-4, 6-9, 11-15, and 18-19 of the '175 Patent. Dkt. No. 39 at 12. Of those asserted claims, claims 1, 9, and 18 are independent and are set forth below to provide context for the claim construction discussion that follows:

1. A vaginal speculum apparatus, said apparatus comprising:
  - a **portable illumination assembly** defined by a housing that retains a portable power supply, at least one LED and an integral curved light pipe made from a light transmissive material, said at least one LED being adjacent to and optically coupled to a proximal end of said integral curved light pipe; and
  - a vaginal speculum comprising an upper blade and a **lower blade**, said **lower blade** including a trough-shaped blade section and a **handle portion** that receives a portion of said **portable illumination assembly** and wherein said **portable illumination assembly**, including said integral light pipe, is **releasably**

**attached** to the **handle portion** of said speculum such that the curved light pipe of said illumination assembly extends into the trough-shaped blade section of said speculum.

9. A vaginal speculum apparatus, said apparatus comprising

a **portable illumination assembly** comprising a portable power source, at least one LED, and a **mechanism for energizing** said at least one LED within a common housing; and

a vaginal speculum having an upper blade a **lower blade**, and a mechanism disposed at a proximal end of said speculum for permitting relative movement between said upper blade and said **lower blade** to enable dilation of a patient, said movement mechanism including a lever portion extending from a proximal end of said upper blade and defining an opening, said **portable illumination assembly** being entirely contained within **the proximal end** of one of said upper blade and said **lower blade** and **releasably attached** thereto and in which **said illumination assembly is accessed for at least one of energization of said at least one LED and removal through said opening.**

18. A vaginal speculum apparatus, said apparatus comprising:

a **portable illumination assembly** comprising a portable power source, at least one LED, and a **mechanism for energizing said at least one LED within a common housing**; and

a vaginal speculum having an upper blade and a lower blade, each of said upper blade and said **lower blade 10** having a distal end and an opposing **proximal end**, and a mechanism for permitting relative movement between said upper blade and said **lower blade** to enable dilation of a patient, said movement mechanism including a

downwardly lever portion extending from the proximal end of said upper blade that engages a yoke extending upwardly from the **proximal end** of said **lower blade**, each of said lever portion and said yoke defining an opening of said speculum, **said portable illumination assembly** being attached to the **proximal end** of one of **20** said upper blade and said **lower blade** and disposed such that the **energization mechanism can be accessed for energizing said at least one LED only through said defined opening.**

'175 Patent, Claims 1, 9, and 18 (disputed terms in bold).

1. Portable Illumination Assembly

The first disputed claim term is "portable illumination assembly." Welch Allyn proposes that the term be construed to mean "a self-contained illumination assembly that is not connected to a non-portable power source, such as a cord or other tether to a power supply." Dkt. No. 36-1 at 9; Dkt. No. 39 at 25. OBP counters that the term should be defined to mean "a fully enclosed housing holding the components of a light, which is attachable and detachable from a speculum without undue effort, disassembly or breakage for ease of moving from one speculum to another for reuse, or for use as a stand-alone examination light." Dkt. No. 36-1 at 9; Dkt. No. 37 at 14-19. Implicated by these competing definitions are several issues, including a disagreement over whether use of the word "portable" implies that the illumination assembly specified in the '175

Patent may not be attached to an external power source by a cord or otherwise. In addition, as can be seen, OBP proposes a limitation that the housing for the light components be attachable and detachable from the speculum for reuse, a limitation that Welch Allyn vigorously contests. The parties also disagree whether the illumination assembly must be fully enclosed within a housing.

Pivotal to this claim term is the word "portable." All three of the independent claims of the '175 Patent refer to both "a portable illumination assembly" and a "portable power supply/source." '175 Patent Claims 1, 9, 18. Dictionary definitions of the term "portable" suggest that the term implies ease of movement or a capability of being readily moved about. *See, e.g., portable, adj. and n.*, Oxford English Dictionary, <http://www.oed.com/view/Entry/148106?redirectedFrom=portable#eid> (last visited Mar. 25, 2016) (defining "portable" as "capable of being moved from place to place; easily carried or conveyed. Also: (designating a device, apparatus, etc.) made smaller and lighter than normal, to enable it to be carried easily"). Courts that have construed claim terms involving the word "portable" have settled on similar definitions. *See, e.g. Comput. Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375-76 (Fed. Cir. 2008) (finding, based upon use in the specification and prosecution

history, that the word "portable" meant "capable of being moved about"); *Marlowe Patent Holdings LLC v. Dice Elecs., LLC*, No. 10-CV-1199, 2015 WL 252026, at \*15 (D. N.J. Jan. 20, 2015) ("The Court construes the disputed term 'portable' as meaning 'capable of being moved about[.]'"); *Broussard v. Go-Devil Mfg. Co. of La., Inc.*, Nos. 08-CV-0124, 08-CV-0125, 2013 WL 3233328, at \*4, (M.D. La. June 25, 2013) (construing the phrase "[a] portable drive assembly having means for a temporary attachment" in a patent involving outdoor motors for use in boats as "portable from one craft to another without undue effort or modification").

Notwithstanding these cases, it is important to construe the claim term at issue with reference to the '175 Patent claims and specifications, viewed from the perspective of a person of ordinary skill in the art at the time of the invention. It is apparent from some of the specification, and its reference to the shortcomings of prior art specula, that the concept of portability was viewed as important by the '175 Patent inventors, and that their intent was to avoid the requirements of power-cord that carried with it certain disadvantages. The '175 Patent specification describes figures 5-7 as depicting the first embodiment of the invention disclosed.'175 Patent, 8:39-41. Describing figure 7, the specification explains that,



[d]ue to the portable and non-tethered (cordless) nature of the illumination assembly **230**, FIG. 7, according to this and other described embodiments that follow, the herein described speculum apparatus **200** is more versatile and can be used, for example, with bed-ridden patients based in part on the fact that there is no corded portion extending from the handle portion from **216**, **216A**.

*Id.* at 16:6-12. At first blush, this portion of the specification, as well as others, suggests that the inventors have acted as their own lexicographers and intended the terms "portable" and "cordless" to be synonymous. See, e.g., '175 Patent, 9:40-45 ("For purposes of reference, the cordless or portable illumination assembly **230** according to this embodiment is at least partially depicted in each of FIGS. **5-8**, **11** and **12**. In brief, this illumination assembly **230** is defined by a housing **236** having a substantially hollow interior that is sized to retain a number of components[.]"); *id.* at 13:20-30 ("In either instance, the corded illumination assembly **140** and the cordless or portable illumination assembly **230** can be installed into the receiving cavity **217** of the handle portion **216** in which the light source contained in each assembly is effectively coupled with the proximal end of a light pipe **254**, FIG. **27**, to uniformly illuminate the target. In the previously described cordless illumination assembly **230**, the light is directed from the contained LED **232**, in part using the reflective interior surface of the spacer tube **241** to the lens **259** that collects the light and

then directs this light to a collecting lens **262**, FIG. **27**[.]"); *id.* at 18:61-67; ("The speculum apparatus **1200**, like the preceding, includes a disposable speculum **1204** as well as an illumination assembly **1260** that is releasably attached to the speculum. In addition and also like the preceding, the speculum **1204** is configured to permit interchangeable attachment of either a corded illumination assembly such as **140**, FIG. **1**, or a cordless (portable) illumination assembly **1260**.").

The following excerpt from the '175 Patent specification, however, undermines this conclusion:

According to yet another aspect claimed herein, there is provided a method of assembling a vaginal speculum apparatus, said apparatus comprising a vaginal speculum having upper and lower blades, said method comprising the steps of releasably attaching a portable illumination assembly to one of said upper blade and said lower blade and configuring said illumination assembly with exterior accessible means to enable energization of a contained LED. *The illumination assembly can be tethered or otherwise connected to a dedicated (e.g., AC) power supply or can include means for receiving at least one battery for powering the at least one LED, such as a white LED.*

'175 Patent, 4:38-49 (emphasis added). Hence, while the '175 Patent specification emphasizes the portability of the speculum and light assembly disclosed – and the fact that they can be cordless – the specification also indicates that this is not necessarily always the case.

Moreover, according to OBP's expert, a person of ordinary skill in the art would not find that the word "portable" precludes the use of a corded or tethered power supply. Dkt. No. 45 at 2-3.

OBP proposes to add the concept of detachability to the definition of this disputed term, providing elaboration as to the extent of detachability that is confusing and adds unnecessary ambiguity. The question of attachability is addressed elsewhere in the three independent claim terms. Independent claims 1 and 9 provide that the portable illumination assembly "is releasably attached to" a portion of the speculum. See '175 Patent, 29:58-60, 30:29-30. Claim 18 states that the portable illumination assembly is "attached to the proximal end of one of said upper blade and said lower blade[.]" *Id.* at 31:19-21. This is consistent with the concept that, under '175 Patent, the entire speculum can be disposed of or, alternatively, the illumination assembly can be removed for further use while the speculum portion only can be discarded. '175 Patent, 4:35-37; see *a/so* Dkt. No. 47-1 at 2-3. Having concluded that the concept of attachability is addressed elsewhere within the asserted claims, I recommend against incorporating it into the construction of this disputed term.

The last issue raised with regard to this claim term is whether the illumination assembly must be fully enclosed within a housing, as urged by OBP. While the '175 Patent specification provides that the illumination assembly is "self-contained," '175 Patent, 12:41-45, 24:14-18, as Welch Allyn argues, self-containment does not necessarily require that the illumination assembly exists in an enclosed housing. The parties are in agreement that the term "housing," as used in claim 1, should be construed as "an enclosure that retains the portable power supply" and that the term "within a common housing," as found in claims 9 and 18, should be interpreted to mean "an enclosure that retains within it the components of a portable illumination assembly." Dkt. No. 39 at 12 n.1. OBP's indirect effort to further limit these agreed constructions should be rejected. Simply stated, there is nothing in the patent specification or elsewhere to constrict this portion of the disputed term to require that the illumination assembly be wholly enclosed within a housing. OBP's proposed construction of the term under consideration should therefore be rejected.

Having carefully considered the arguments of the parties, I recommend that the term "portable illumination assembly" be defined as "a

self-contained illumination assembly that can be easily moved from place-to-place."

## 2. Switch / Mechanism for Energizing

Certain of the claims within the '175 Patent provide for a means of energizing the LED illumination component specified. Claims 4, 15, and 19 describe the mechanism for energizing the LED illumination source as comprising a "switch." '175 Patent, 30:3, 30:49, 31:26. Claims 3, 9, and 18 refer to the device through which activation occurs more generally as a "mechanism for energizing." *Id.* at 29:66, 30:17-18, 31:16-17. Welch Allyn proposes that the term "switch" be construed as a "structure that can be acted upon to energize the LED" and that, relatedly, "mechanism for energizing" be defined as a "structure that can energize the LED." See, e.g., Dkt. No. 39 at 12. OBP, in contrast contends that the term "switch" needs no construction, and that the term "mechanism for energizing" should be defined under 35 U.S.C. § 112(f) as "a slider switch with a conductive strip; a rotary switch with a conductive strip; an optical switch; a magnetic/reed switch; an ON/OFF throw switch that can be enabled with the speculum when engaged therewith to automatically or manually energize or de-energize the LED; and equivalents of the foregoing switches under Section § [sic] 112(f)." See, e.g., Dkt. No. 36-1 at

2, 3. Alternatively, OBP argues that "mechanism for energizing" should be defined as "a device that includes a conductive part that connects the conductors of an LED to a power source in order to energize the LED." *Id.* at 3.

The primary dispute with respect to this claim is whether it represents a "means-plus-function" limitation. Had the term read "means for energizing," it would have been clear that a means-plus-function limitation was stated. See *Personalized Media Commc'ns, LLC*, 161 F.3d at 703-04 ("[U]se of the word 'means' creates a presumption that § 112, ¶ 6 applies, and that the failure to use the word 'means' creates a presumption that § 112, ¶ 6 does not apply."). OBP argues that substitution of the word "mechanism" makes it no less a means-plus-function term. Dkt. No. 37 at 21-22.

Means-plus-function claim terms are authorized under 35 U.S.C. § 112, ¶ 6, which provides as follows:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, ¶ 6.<sup>9</sup>

This issue was addressed by the Federal Circuit in its relatively recent decision in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015). That case involved a patent describing "methods and systems for 'distributed learning' that utilize industry standard computer hardware and software linked by a network to provide a classroom or auditorium-like metaphor—i.e., a 'virtual classroom' environment." *Williamson*, 792 F.3d at 1343. The Federal Circuit explained that there are exceptions to the normal rules regarding the above-described presumptions with respect to the use of the word "means," noting that it has never "blindly elevated form over substance when evaluating whether a claim limitation invokes § 112." *Williamson*, 792 F.3d at 1348. The court "emphasized that the essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as to the name or structure." *Id.* at 1348-49 (citing *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996)).

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<sup>9</sup> As was stated earlier, the AIA amended section 112 to assign letters to the previously unnumbered paragraphs. The language of section 112, ¶ 6 is now section 112(f), as OBP notes. Dkt. No. 37 at 21. Because the patent application that ripened into the '175 Patent was filed prior to the effective date of the AIA, however, the issue is controlled by the former version. *Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App'x 963, 967 n.3 (Fed. Cir. 2015).

In this instance, the operative claim term is "mechanism." As the Federal Circuit noted,

[g]eneric terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke section 112, para. 6.

*Williamson*, 792 F.3d at 1350 (citing *Mass. Inst. of Tech. and Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006)).

Having carefully considered the matter, I recommend a finding that the use of the term "mechanism" falls within the ambit of *Williamson*, and that this disputed term should therefore be interpreted as stating a means-plus-function claim term.

Having reached that conclusion, I must next determine whether the patent specification discloses sufficient structure to correspond to the claimed function. *Williamson*, 792 F.3d at 1351. The function to be served by the corresponding structure is set out in the disputed claim term – that is, to energize the LED source of the patented speculum. In this instance, the '175 Patent specification and claims themselves provide significant guidance as to the nature of the structure designed to perform this function. Claim 15, for example, specifies "[a]n apparatus as recited in



Claim 9 wherein said energizing mechanism comprises a switch." '175 Patent, 31:48-49. The '175 Patent specification identifies several structures that can perform the function of energizing the LED illumination, including (1) a slider switch with a conductive strip, *id.* at 12:5-14; (2) rotary switch with a conductive strip, *id.* at 20:64 – 21:4; (3) an optical switch, *id.* at 12:36, 21:6; (4) a magnetic/reed switch, *id.*; and (5) an ON/OFF throw switch that can be enabled the speculum when engaged therewith to automatically or manually energize and de-energize the LED, *id.* at 12:37. These portions of the specifications provide sufficient detail regarding the types of structure corresponding to the claimed function to enable the court to adopt a means-plus-function construction of this disputed term. I therefore recommend that the term "mechanism for energizing" be defined as "a slider switch with a conductive strip; a rotary switch with a conductive strip; an optical switch; a magnetic/reed switch; an ON/OFF throw switch that can be enabled with the speculum when engaged therewith to automatically or manually energize and de-energize the LED; and equivalents of the foregoing switches."

The other claim term in this subgroup is "switch." OBP argues that the term need not be construed by the court, while Welch Allyn suggests the term be defined as a "structure that can energize the LED." Dkt. No.

36-1 at 3. Because OBP's vaginal speculum utilizes a pull-tab to energize the LED source, Welch Allyn insists the court construe the term "switch" so as to preclude OBP from arguing at trial that pull-tabs should be excluded from the definition of the term. Dkt. No. 39 at 14-15. It is true, of course, that "[a] claim is construed in light of the claim language, the other claims, the prior art, the prosecution history, and the specification, *not* in light of the accused device." *SRI Int'l*, 775 F.2d at 1118. It is also true, however, that a court is dutibound to determine the scope of a patent claim term for the jury when necessary to resolve the parties' disagreement regarding construction. *O2 Micro Int'l Ltd.*, 52 F.3d at 1361-62. This obligation arises only "when a term has more than one 'ordinary' meaning or when reliance on the term's 'ordinary' meaning does not resolve the parties' dispute." *Id.* at 1361.

In this case, in the '175 Patent specification the inventors have not acted as their own lexicographers and provided a definition of the term "switch," and, although only one makes logical sense in the context of the patent, there are admittedly several "ordinary" meanings of the disputed term. See, e.g., *switch*, *n.*, Oxford English Dictionary <http://www.oed.com/view/Entry/195965?rskey=QJlzMz&result=1#eid> (last visited Mar. 25, 2016) (defining "switch" first as (1) "[a] slender tapering

riding whip," (2) "stimulus, incentive," (3) "[a] thin flexible shoot cut from a tree," and (4) "[a] massage instrument made of twigs" before providing "a lever, plug, or other device for making or breaking a contact, or altering the connections of a circuit" as a definition). In light of the differing ordinary meanings of the word "switch," and because the parties have presented the court with a clear disagreement with respect to this term, I recommend construing the term "switch" to mean "[a] lever, plug, or other device for making or breaking contact, or altering the connections of a circuit," which comes closest to representing an "ordinary" meaning of the disputed term in the context of the '175 Patent specification.

3. Said Speculum Is Disposable / The Entire Apparatus Is Disposable

The next two claim terms to be construed implicate the concept of disposability. Claim 7, which is dependent upon claim 1, and claim 11, which is dependent upon claim 9, disclose an apparatus in which the speculum recited is disposable. '175 Patent Claims 7, 11. Claims 8 and 12, which are dependent upon the same two independent claims, respectively, provide that the entire apparatus referenced in the claims is disposable. *Id.*, Claims, 8, 12.

The parties agree that, as it relates to medical instruments, the term "disposable" is generally understood to designate a device that is

designed for single use. See, e.g., Dkt. No. 37 at 28. The specification in this instance uniformly supports Welch Allyn's proposed definition and the notion that disposability implies single use or single patient use.<sup>10</sup> See, e.g., '175 Patent, 1:20-24 ("This application generally relates to the field of hand-held medical diagnostic instruments, and more particularly to a vaginal speculum apparatus including a single-use or single patient speculum that distributes illumination from at least one illumination assembly attached to the speculum."); *id.* at 4:35-37 ("According to one version, the speculum is disposable[.] Alternatively, the entire apparatus, including the illumination assembly, is disposable."); *id.* at 24:44-46 ("Alternatively, the speculum **710** and illumination assembly **704** can each be discarded following single or single patient use."); *id.* at 29:40-44 ("[T]he illumination assembly discussed with regard to each of the embodiments can be either a disposable version or, as described by a number of embodiments herein, a reusable assembly that can be attached to a disposable speculum.").

Welch Allyn's proposed constructions of these terms appear to embody this concept, suggesting the court construe "said speculum is

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<sup>10</sup> OBP describes its accused device, called the ER-SPEC, as a "[d]isposable, single-use device," suggesting that OBP similarly understands the term "disposable" to refer to a product intended for a single-use. Dkt. No. 39-13 at 2.

disposable" to mean "the speculum is designed to be discarded after a single use or a single patient use," and the related term "the entire apparatus is disposable" be construed as meaning "the entire apparatus is designed to be discarded after a single use or a single patient use." See, e.g., Dkt. No. 36-1 at 4. Before proposing a construction for "the entire apparatus is disposable," OBP argues that the term is indefinite, and invites the court to weigh in on that question at this juncture, rather than in the context of its invalidity defense and counterclaim. *Id.* Because the term appears to be readily understood by those in the field, as OBP concedes, I recommend that the court assign a construction to it and defer the indefiniteness analysis for resolution at a later procedural juncture.

When offering a definition of these terms, OBP adds further requirements that, frankly, do not appear anywhere in the claims, patent specification, or prosecution history. It posits, for example, that the disposable speculum must be made of "molded plastic such as acrylic or polystyrene," Dkt. No. 36-1 at 4, while the specification neither calls for the patented device to either be comprised of "molded plastic" or "acrylic or polystyrene." Similarly, OBP's suggests that disposal must occur "in a standard waste disposal facility" and that the overall end-user cost be competitive with multiple use counterparts, without citing to any support for

these propositions from the specification.<sup>11</sup> The only support for these further limitations is found in the declaration of OBP's expert, Carl R. Leinsing. Dkt. No. 38 at 27. Absent ambiguity, however, Leising's opinions are of limited value to the court, and serve solely as an attempt to interject requirements finding no support in the patent claims and specifications.

A careful review of the specification in this matter yields no support for the additional restrictions now proposed by OBP, including a limitation on the types of materials out of which the specified speculum and apparatus may be constructed and the method of its disposal. Accordingly, I recommend that the court construe the term disposable as consistent with what OBP concedes is understood by persons of ordinary skill in the art, and that Welch Allyn's constructions of "said speculum is disposable" ("the speculum is designed to be discarded after a single use or a single patient use") and "the entire apparatus is disposable" ("the entire apparatus is designed to be discarded after a single use or a single patient use") be adopted.

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<sup>11</sup> OBP proposes that the term "said speculum is disposable" be construed to mean "a three piece vaginal speculum with three parts being made of molded plastic such as acrylic or polystyrene" and that the term "the entire apparatus is disposable" be defined to mean "a device designed for single use that is made of fewer parts and less expensive material than its reusable counterpart, that is not designed for re-sterilization and that can be disposed of in a standard waste disposal facility with an overall end user cost that is competitive with a multiple use counterpart device." Dkt. No. 36-1 at 4.

4. Said Illumination Assembly Is Accessed . . . Through Said Opening / Can be Accessed . . . Only Through Said Defined Opening

Independent claim 9 of the '175 Patent provides, in relevant part, for an illumination assembly that "is accessed for at least one of energization of said at least one LED and removal through said opening." '175 Patent, 30:30-32. Claim 9 specifies an opening defined by a movement mechanism that includes a lever portion extending from the proximal end of the upper blade. *Id.* at 30:20-26. Claim 18 provides that the energization mechanism for the LED "can be accessed for energizing said at least one LED only through said defined opening," and specifies an opening defined by a movement mechanism that comprises a lever portion extending from the proximal end of the upper blade that engages a yoke extending upwardly from the proximal end of the lower blade. *Id.* at 31:9-24. The parties disagree over the meaning of these terms, and specifically quarrel over the concept of accessibility. *Compare* Dkt. No. 37 at 25-26 *with* Dkt. No. 39 at 18-20. In addition, OBP argues that the claim 9 language is indefinite because it specifies both an apparatus and a method. Dkt. No. 37 at 23-25.

In advancing its indefiniteness argument, OBP places reliance upon the Federal Circuit's decision in *IPXL Holdings, L.L.C. v. Amazon.com*,

*Inc.*, 430 F.3d 1377 (Fed. Cir. 2005). In that case, as a matter of first impression, the Federal Circuit concluded that a patent claim that recites both an apparatus and a method of using the apparatus is impermissibly indefinite under 35 U.S.C. § 112, ¶ 2.<sup>12</sup> *IBXL Holdings, L.L.C.*, 430 F.3d at 1384. Relying on the rationale set forth by the Board of Patent Appeals and Interferences of the PTO, in that case the Federal Circuit explained that,

as a result of the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus.

*Id.* The confusion existing under these circumstances renders the claim insufficiently precise under 35 U.S.C. §112, ¶ 2. *Id.*

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<sup>12</sup> The claim at issue in *IPXL Holdings, L.L.C.* that was found to be indefinite as representing a hybrid apparatus and method claim reads as follows:

The *system of claim 2* [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and *the user uses the input means* to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

*IPXL Holdings, L.L.C.*, 430 F.3d at 1384 (emphasis and alteration in original).



Relying upon *IPXL Holdings, L.L.C.*, OBP argues that the term "is accessed" is not the functional equivalent of "is accessible" and describes a method rather than an apparatus. Dkt. No. 37 at 25-26. In further support of that position, OBP notes that during the course of patent prosecution, in response to a rejection based upon a specific prior art reference, Welch Allyn deleted the phrase "is accessible" in claim 9 and substituted "is accessed." Dkt. No. 39-6 at 64. OBP maintains that Welch Allyn is therefore now estopped from recovering what it relinquished during patent prosecution, namely that the illumination assembly is accessible through the specified opening.

"Prosecution disclaimer occurs when a patentee, either through argument or amendment, surrenders claim scope during the course of prosecution." *Heuft Systemtechnik GMBH v. Indus. Dynamics Co., Ltd.*, 282 F. App'x 836, 839 (Fed. Cir. 2008). Amendments that are "vague, ambiguous, or subject to other reasonable interpretation[, however,] are not sufficient to surrender claim scope." *Heuft Systemtechnik GMBH*, 282 F. App'x at 839. A patentee's intent must be "clear and unmistakable" in order for prosecution disclaimer to attach. *Id.* (quotation marks omitted).

A review of the patent prosecution history in this case makes it clear that the amendment that resulted in the change from "is accessible" to "is

accessed" was intended to distinguish a prior art speculum that could not be accessed through the defined opening for either energization or removal. This becomes clear from consideration of the following excerpt of the patentee's explanatory communication to the PTO:

Regarding claim 11, this claim has now been amended to specify the portable illumination assembly is accessible through an opening defined at the proximal end of the upper and lower blade. The opening, as described in general at paragraph [00134] of the present specification as well as Figs. 28 and 35-37, at a minimum, is formed by a lever portion at the proximal end of the upper blade. The lever portion is provided as part of a movement mechanism that enables relative movement of the upper and lower blades of the speculum to permit dilation of a subject wherein the defined opening typically permits viewing by a user. In the present embodiment, and as clearly shown in Figs. 35-37 and paragraphs [00139] — [0142], when attached to one of the upper and lower blades, the portable illumination assembly is entirely contained within the proximal end of one of the upper and lower blades and releasably attached thereto such that the illumination assembly is accessed for at least one of energization of the at least one LED and removal through the opening. Therefore, no new matter has been added.

As previously discussed, Moore describes an adaptive light carrier element that permits a diagnostic instrument handle to be used in conjunction with a vaginal speculum. The adaptive element, which retains a plurality of optical fibers, is inserted into a receiving cavity in the handle portion of the speculum and is optically coupled to the proximal end of an integral light pipe of the

speculum and the light source separately contained in the instrument handle. Claim 11, as amended, clearly requires that the portable illumination assembly comprising a portable power supply and at least one LED retained within a common housing be accessible through the opening defined in the proximal end of the speculum and more specifically, the upper and lower blades. The speculum of Moore includes a similar opening, but clearly the illumination assembly cannot possibly be accessed through the defined opening, see Fig. 9 of Moore, whether for energization or removal.

The supplemental teachings of Wawro fail to include or even suggest the above-noted missing features. Even if one were to arguably interpret the LED and battery of this secondary reference provide an illumination assembly per se', accessing either would require removing the above components through the handle. Access via an opening defined in the proximal end of the Moore speculum would be impossible. Therefore and because this recited feature is entirely missing from the cited prior art, amended claim 11 is patentably distinct.

Dkt. No. 39-6 at 71-72 (emphasis in original). While it is unclear why the change was made from "is accessible" to "is accessed," there is no indication of any clear and unmistakable relinquishment of "is accessible."

Having carefully considered the patent specification and prosecution history, I recommend that the court not construe this disputed term as specifying a step that the user must take in accessing the illumination assembly for energization and/or removal, and instead that the claim term



that the court construe the term as "the portable illumination assembly can be energized and/or removed through the opening."

The more troublesome of these terms is that which appears in claim 18 of the '175 Patent. The controversy regarding this term centers upon the word "only." OBP suggests that the use of this word means that if it is plausible under any circumstances to access the means for energizing the LED other than through the opening, then infringement does not occur. Dkt. No. 37 at 26-27.

It is true that the word "only" should factor into the construction of this term because "all claim terms are presumed to have meaning in a claim." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004). The ordinary meaning of the word "only" is "solely" or "exclusively." *Elekta Inst. S.A. v. O.U.R. Sci. Int'l*, 214 F.3d 1302, 1307 (Fed. Cir. 2000). Welch Allyn's proposed definition would write the term "only" out of the claim.

This notwithstanding, I find that OBP's proposed definition is far too demanding in its effort to equate "only" with "impossibility." It is clear from the specification and claim 18 itself that what was intended by the inventors was a design by which the portable illumination assembly would ordinarily be energized only by accessing the energization mechanism

through the opening formed by the shape of the yoke and lever portion. Nowhere in the patent specification or otherwise have the inventors suggested that it should be physically impossible to access the switch or other energization mechanism other than through the opening. Accordingly, I recommend that Welch Allyn's proposed definition of "can be accessed . . . only through said defined opening" be accepted, with modification, and the term be construed to mean "the portable illumination assembly is designed to be energized only by accessing the energization mechanism through the opening formed by the yoke and the lever portion."

#### 5. Releasably Attached

Independent claims 1 and 9 of the '175 Patent specify a portable illumination assembly that is "releasably attached" – in claim 1 to the handle portion of the speculum and in Claim 9 to the proximal end of one of the upper blade and lower blade. '175 Patent, Claims 1, 9. As a proposed construction of this term, Welch Allyn offers what appears to represent a common-sense construction, "able to be detached." Dkt. No. 36-1 at 8. OBP, on the other hand, suggests that further elaboration is necessary, proposing that the term be defined to mean "the portable illumination assembly is capable of being separated intact from the

speculum without the use of tools and without breakage or disassembly."  
*Id.*

Once again, relying almost exclusively upon the declaration of its expert, Carl R. Leinsing, OBP argues that a person of ordinary skill in the art would understand that something that is releasably attached to a portion of a medical device can be separated intact without the use of any tools, breakage, or disassembly. Dkt. No. 37 at 19-20. The specification of the '175 Patent, however, does not support such a restrictive interpretation. There is nothing in the specification that precludes the use of at least some simple tools in the separation process. I note, for example, that when describing one exemplary embodiment of the '175 Patent, the patent specification provides as follows:

The housing **508** is releasably attached to the top blade **512** according to this embodiment although the housing can be alternatively positioned relative to either the top blade or the lower blade **516** of the speculum **510**, as discussed herein. *Clips, fasteners or other conventional means can be used to releasably attach the housing **508** to the blade **512**, wherein the illumination assembly **504** can also be used separately as an examination light when detached.*

'175 Patent, 23:13-21 (emphasis added). While the specification does not provide any further explanation of the terms "clips, fasteners, or other conventional means," nowhere in the specification or claim language does

it suggest that tools cannot be used during the detachment process. OBP clings to the absence of an explanation for those terms in support of its position that detaching a "releasably attachable" illumination assembly requires no tools, but, as Welch Allyn emphasized during oral argument, a screw is an example of a type of fastener that requires the use of a tool to secure (or fasten) it. See, e.g., *Caught Fish Enters., LLC v. Contek, Inc.*, 509 F. Supp. 2d 954, 962 (D. Colo. 2007) (determining that the term "'blunt-nose screw' simply means a fastener with [a] spirally grooved shaft and rounded end"); *fasten*, v., Oxford English Dictionary <http://www.oed.com/view/Entry/68428?rskey=liCc10&result=2&isAdvanced=false#eid> (last visited Mar. 25, 2016) (defining "to fasten" as "to fix or hold securely in position"). Consequently, it would be error, and contrary to this portion of the specification, to conclude that the use of a tool to remove the portable illumination assembly from the speculum would negate a finding of releasable attachment.

I conclude that neither party's proposed construction of this term precisely captures the essence of the intent of the inventors, and instead recommend that the term "releasably attached" be construed to mean simply "capable of being easily detached."



## 6. Lower Blade / Handle Portion / Proximal End

Apparently in response to some of OBP's earlier indefiniteness contentions, Welch Allyn has suggested that "lower blade," "handle portion," and "proximal end" require construction by the court. Dkt. No. 39 at 20-23. OBP, however, has explained that it withdrew its indefiniteness contention with respect to claim 14 as of April 17, 2015, and now argues there is no reason for the court to undertake construction of these terms. Dkt. No. 44 at 27. In addition, at oral argument in this matter, the parties agreed that the "proximal end" – the term garnering the most attention from the parties – is the end of the speculum that faces the user. Dkt. No. 54 at 117, 120. While Welch Allyn suggests that it is necessary to construe "proximal end" at least to the extent that a construction would include the demarcation of where it begins and ends, I see no reason to do so at this juncture in the absence of any real dispute between the parties.<sup>13</sup> See *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1318-19 (Fed. Cir. 2007) ("When there is no dispute as to the meaning of a term that could affect the disputed issues of the litigation, 'construction' may not be

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<sup>13</sup> Welch Allyn contends that the other two terms, "lower blade" and "handle portion," should be defined simply because it believes those terms "go together" with the term "proximal end." Dkt. No. 54 at 122. Indeed, Welch Allyn concedes "lower blade" and "handle portion" are not contested, *id.*, and I do not agree that they are so intertwined with "proximal end" that the court must construe the three terms together, if at all.

necessary."). Accordingly, I recommend that the court not construe these three remaining claim terms.

#### IV. SUMMARY AND RECOMMENDATION

Based upon the parties' oral and written presentations, and having carefully considered the available intrinsic evidence and, to the limited extent necessary, extrinsic evidence, it is hereby respectfully RECOMMENDED that the court adopt the following constructions of the claim terms at issue in this matter:

##### (1) Agreed Upon Terms

<u>Term/Phrase</u>	<u>Agreed Construction</u>
integral curved light pipe	a component of the portable illumination assembly that transmits light
receives	the handle portion itself (not some other component) holds or contains a portion of the portable illumination assembly
set of rails	a pair of substantially straight structures (for example, a track) on the handle portion that aligns and retains a portion of the portable illumination assembly
housing	an enclosure that retains the portable power supply
within a common housing	an enclosure that retains within it the components of the portable illumination assembly

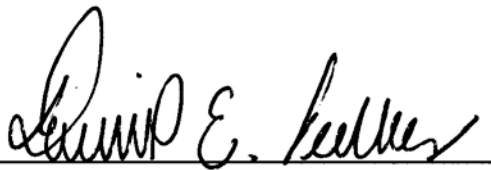
## (2) Claims in Dispute

<u>Term</u>	<u>Construction</u>
portable illumination assembly	a self-contained illumination assembly that can be easily moved from place-to-place
switch	a lever, plug, or other device for making or breaking contact, or altering the connections of a circuit
mechanism for energizing	a slider switch with a conductive strip; a rotary switch with a conductive strip; an optical switch; a magnetic/reed switch; an ON/OFF throw switch that can be enabled with the speculum when engaged therewith to automatically or manually energize and de-energize the LED; and equivalents of the foregoing switches
said speculum is disposable	the speculum is designed to be discarded after a single use or a single patient use
the entire apparatus is disposable	the entire apparatus is designed to be discarded after a single use or a single patient use
said illumination assembly is accessed . . . through said opening	the portable illumination assembly can be energized and/or removed through the opening
can be accessed . . . only through said defined opening	the portable illumination assembly is designed to be energized only by accessing the energization mechanism through the opening formed by the yoke and the lever portion
releasably attached	capable of being easily detached
lower Blade	no construction necessary
handle Portion	no construction necessary
proximal End	no construction necessary

NOTICE: Pursuant to 28 U.S.C. § 636(b)(1), the parties may lodge written objections to the foregoing report. Such objections must be filed with the clerk of the court within FOURTEEN days of service of this report. FAILURE TO SO OBJECT TO THIS REPORT WILL PRECLUDE APPELLATE REVIEW. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 6(a), 6(d), 72; *Roldan v. Racette*, 984 F.2d 85 (2d Cir. 1993).

It is hereby ORDERED that the clerk of the court serve a copy of this report and recommendation upon the parties in accordance with this court's local rules.

Dated: March 31, 2016  
Syracuse, New York

  
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David E. Peebles  
U.S. Magistrate Judge